

Abstract:

Process for the production of virus-inactivated human gammaglobulin G.

5 The gammaglobulin is extracted from a fraction isolated by fractionation with ethanol in the presence of a carbohydrate, and after reducing the content of contaminants with PEG, it is applied to an anionic resin exchange column, an effluent being obtained in which the PEG content is 10 subsequently reduced by ultrafiltration and which is concentrated in order to carry out sequentially an optional treatment at an acid pH and at least one of the following steps of viral inactivation, consisting of pasteurisation and a treatment with solvent/detergent, the product 15 afterwards being precipitated and washed with PEG in order to eliminate any chemical viral inactivation reagents and then, by solubilisation and change of pH, the protein contaminants, and finally purified by ultrafiltration to reduce the volume and the PEG content, then carrying out an 20 optional virus filtration and subsequent concentration to a protein value of 5% or 10%.

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